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State Health Advisory Supplement Pfizer COVID-19 Vaccine Authorized for Ages 5-11

Coronavirus Disease 2019 Supplemental Advisory #13.4 Wyoming Department of Health November 3, 2021

SITUATION SUMMARY

The U.S. Food and Drug Administration (FDA) has authorized under emergency use and the Centers for Disease Control and Prevention (CDC) has recommended the Pfizer-BioNTech COVID-19 vaccine for children aged 5 to 11 years. CDC and WDH recommend that children aged 5 to 11 years receive a two dose series of the Pfizer-BioNTech vaccine using a 10 mcg dose for each inoculation. Wyoming providers may immediately begin providing the Pfizer-BioNTech COVID-19 vaccine to children aged 5 to 11 years according to the FDA emergency use authorization and CDC recommendation.

DOSING AND ADMINISTRATION

The Pfizer-BioNTech COVID-19 vaccine for children aged 5-11 years is supplied in a different vial and a different formulation than that authorized for individuals aged 12 years and older. The vial for children aged 5-11 years is supplied in a multiple dose vial with an orange cap and a label with an orange border. The vial requires dilution with 1.3mL sterile 0.9% sodium chloride injection prior to use. Each vial contains 10 doses.

Children aged 5-11 years should receive two doses consisting of 10 mcg (0.2 mL) per dose. Doses should be separated by three weeks (21 days). The 10 mcg dose is one-third of the dose authorized for individuals aged 12 years and older and was selected based on safety, tolerability, and immunogenicity data.

The Pfizer vaccine authorized for individuals aged 12 and older (adolescent and adult vaccine) **cannot** be used interchangeably with the vaccine authorized for individuals aged 5-11 (pediatric vaccine), nor can pediatric vaccine be used for adults.

The FDA fact sheet for healthcare providers for the Pfizer-BioNTech COVID-19 vaccine authorized for children aged 5-11 years can be found here: https://www.fda.gov/media/153714/download

The FDA fact sheet for patients and caregivers for the Pfizer-BioNTech COVID-19 vaccine authorized for children aged 5-11 years can be found here:

https://www.fda.gov/media/153717/download

CLINICAL CONSIDERATIONS

Updates to CDC's Interim Clinical Considerations are forthcoming. The updates will be published here as soon as they are available:

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Key clinical considerations in children aged 5-11 years include the following:

- The Wyoming Department of Health (WDH) and CDC recommend this vaccine for 5-11 year olds regardless of a history of previous COVID-19 infection
- Children should receive the age-appropriate vaccine formulation regardless of their size or weight. Vaccine dosage is based on age and not size or weight
- The CDC recommends that the dosage should be based on the child's age on the day of vaccination
 - If a child turns from 11 to 12 years of age in between their first and second dose, they should receive 5-11 year old 10 mcg formulation for their first dose and the the ≥12 years 30 mcg formulation for their second dose
 - o If a child turns 12 between their first and second dose and received the 5-11 year old 10 mcg dose for their second dose, they do not need to repeat the dose and this is not considered an error per the emergency use authorization
- COVID-19 vaccine may be administered without regard to the timing of other vaccines (co-administration)

CDC will host a COCA call on Thursday, November 4th from 12-1PM MT (Pediatric COVID-19 Vaccines: CDC's Recommendations for COVID-19 Vaccine Primary Series in Children 5-11 years old). Further information can be found here: https://emergency.cdc.gov/coca/calls/2021/callinfo 110421.asp

DISTRIBUTION

Initial shipments of pediatric Pfizer-BioNTech vaccine for children aged 5-11 years have been distributed to the public health nursing offices and local health departments in Wyoming counties. COVID-19 vaccine providers who serve patients aged 5-11 years are encouraged to work with public health agencies in your county to receive an appropriate number of doses from that agency. If you need any assistance, please reach out to the Immunization Unit at wdh.immunize@wyo.gov.

Beginning the week of November 8, additional vaccine will be available for COVID-19 Vaccine Providers to order through standard WDH Immunization Unit ordering processes.

COVID-19 Vaccine Providers will receive further information about vaccine storage and transfer from the Immunization Unit.

CONTACT INFORMATION

For questions about the COVID-19 vaccines, providers should visit the WDH Immunization Unit website at

https://health.wyo.gov/publichealth/immunization/wyoming-covid-19-vaccine-information/ or email WDH.immunization@wyo.gov.

Wyoming healthcare providers and facilities are reminded to check COVID-19 resources available from <u>WDH</u> and <u>CDC</u>. Healthcare providers or facilities can contact WDH through the following channels:

- Please email questions about preparedness, PPE, infection control, or other non-urgent topics to wdh.covid19@wyo.gov. This email address is monitored 7 days a week and replies will come within 24 hours.
- Please contact WPHL with questions about specimen collection, storage, or shipping at 307-777-7431 or WPHL@wyo.gov.
- Please use the WDH Public Health Emergency Line (1-888-996-9104) for urgent questions. This line is intended ONLY for healthcare providers. Do not share this number with the public.

Please refer questions from the general public to 211 or to the WDH email box (wdh.covid19@wyo.gov).